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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,107	09/30/2003	Michael A. Wack	DEP-673CIP2	4990

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EXAMINER
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RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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04/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,107	<b>Applicant(s)</b> WACK ET AL.	
	<b>Examiner</b> Anu Ramana	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-28 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/22/08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 22, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 23 and 24, "said first bushing" and "said second bushing" lack antecedent basis.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Aikins et al. (US 2003/0040748 A1).

Aikins et al. disclose a guide including: a body having a riser 170; a first targeting guide 196; and a sheath 202 fittable to the body. Aikins et al. further disclose a compression drill guide 204 slidably fittable within the elongate bore of the sheath; and a noncompression drill guide or tap sleeve slidably fittable within the elongate bore of the sheath (Figs. 18 and 21 and paras [0076]-[0078]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herzenberg et al. (US 5,403,322) in view of Miller (US 2,424,485).

Herzenberg et al. disclose a guide including: a body having a riser 12c; a first targeting guide 11; a drill sleeve or tube 46 capable of being fitted to the body; and a sleeve or bushing 56 received in the tube wherein the external surface 56 of bushing is sized and shaped to fit in the bore 52 of tube 46 (Figs. 1 and 8-10, col. 4, lines 30-68, cols. 5-7 and col. 8, lines 1-13).

Herzenberg et al. disclose all elements of the claimed invention except for a tube having an elongate bore with a non-circular transverse cross section.

Miller teaches tapering the external surface of a bushing and tapering the bore 8 of the liner or sleeve in which the bushing is received to provide a tight fit between the bushing and the liner (Fig. 2 and col. 2, lines 18-48).

It would have been obvious to one of ordinary skill in the art to taper the internal surface of the bore of Herzenberg et al. tube to provide a tight fit with the

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bushing received in the tube as taught by Miller. Using the known technique of providing a taper to the inner bore of the Herzenberg et al. tube, or providing a non-circular transverse cross section would have been obvious to one of ordinary skill.

Regarding claim 21, Herzenberg et al. disclose their guide to have a radiolucent body (col. 3, lines 47-52).

Regarding claim 22, bushing 56 has a threaded portion 47 (col. 7, lines 28-36).

Regarding claim 23, bushing 56 has teeth or bushing protrusions 64 (col. 7, lines 25-27).

Regarding claim 24, tube 46 has a tube locating feature or knob 50 and bushing 56 has a bushing location feature or knob 60 (col. 7, 37-55).

Regarding claim 25, although the combination of Herzenberg et al. and Miller does not disclose a plurality of bushings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a plurality of bushings, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 28, Herzenberg et al. disclose providing a kit including a first targeting guide 11 and a second targeting guide 40 (col. 5, lines 52-59).

Claims 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. (US 5,312,409) in view of Cartwright et al. (US 5,192,293).

McLaughlin discloses a guide including: a body having a riser 2 and a first targeting guide 4; and a tube or first bushing fittable in guide 4 wherein the bushing may be of different shapes and sizes depending on the shape and size

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of the drill bit being used in the surgical operation (Figs. 1 and 2 and col. 3, lines 15-25).

Regarding claim 25, the Examiner is interpreting a second bushing of a different size from the first bushing to be the alignment fastener bushing.

McLaughlin discloses all elements of the claimed invention except for the bushing to have an elongated bore with a non-circular cross section.

Cartwright et al. teach providing various adapter inserts or bushings for a drill guide or tube wherein the adapter inserts are configured to closely conform to the drill nose. Cartwright et al. also teach an adapter insert or bushing having an elongated bore that is tapered or has a non-circular transverse cross section for use with a specific drill nose (col. 3, lines 3-26).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a bushing having a non-circular transverse cross section in the McLaughlin et al. device, as taught by Cartwright et al., so that the bushing closely conforms to the shape of the drill nose.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. (US 5,312,409) in view of Cartwright et al. (US 5,192,293), further in view of Levy (US 5,540,695).

The combination of McLaughlin et al. and Cartwright et al. discloses all elements of the claimed invention except for a portion of the guide being made of a radiolucent material.

Levy teaches making a drill guide of a radiolucent material so that fluoroscopy can be utilized to align the drill guide (col. 6, lines 39-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed a portion of the guide of the combination of McLaughlin et al. and Cartwright et al., for example the bushing, of radiolucent

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material, as taught by Levy, so that fluoroscopy can be used to check alignment of the guide.

Claims 19-20, 25-27 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aikins et al. (US 2003/0040748 A1) in view of Cartwright et al. (US 5,192,293), further in view of Miller (US 2,424,485).

Aikins et al. disclose all elements of the claimed invention except for the elongate bores of the sheath or tube, compression drill guide or first bushing and noncompression drill guide or alignment fastener bushing or second bushing to have non-circular transverse cross sections.

Cartwright et al. teach providing various adapter inserts or bushings for a drill guide or tube wherein the adapter inserts are configured to closely conform to the drill nose. Cartwright et al. also teach an adapter insert or bushing having an elongated bore that is tapered or has a non-circular transverse or oval transverse cross section for use with a specific drill nose (col. 3, lines 3-26).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a bushing having a non-circular or oval transverse cross section to the elongated bore of the Aikins et al. compression drill guide or noncompression drill guide, as taught by Cartwright et al., so that the drill guide or bushing closely conforms to the shape of the drill nose.

The combination of Aikins et al. and Cartwright et al. disclose all elements of the claimed invention except for the sheath or tube to have an elongate bore with a non-circular transverse cross section.

Miller teaches tapering the external surface of a bushing and tapering the bore 8 of the liner or sleeve or tube in which the bushing is received to provide a tight fit between the bushing and the liner (Fig. 2 and col. 2, lines 18-48).

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Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have tapered the internal walls of the bore in the sheath of the device of the combination of Aikins et al. and Cartwright et al. to provide a tight fit with the bushing received in the tube as taught by Miller. Using the known technique of providing a taper to the inner bore of the sleeve of the combination of Aikins et al. and Cartwright et al., or providing a non-circular or oval transverse cross section would have been obvious to one of ordinary skill.

Regarding claims 35 and 36, Miller teaches providing an eccentric bore 13 in a bushing so that minute adjustments to the position of the drilled hole are possible (Fig. 6 and col. 3, lines 32-36).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided eccentric bores to each of the compression drill guide or first bushing and the noncompression drill guide or second bushing, respectively, in the device of the combination of Aikins et al. and Cartwright et al., as taught by Miller, to enable minute adjustments to the position of the drilled hole.

Regarding claim 37, Miller teaches providing a knurled shoulder flange 12 or visualization guide on a bushing to enable gripping and maneuvering of the bushing with respect to the liner or sleeve or sheath or tube in which the bushing is received (col. 2, lines 36-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a knurled shoulder flange or visualization guide to the compression drill guide or first bushing and the noncompression drill guide or second bushing in the device of the combination of Aikins et al. and Cartwright et al., as taught by Miller, to enable gripping and maneuverability of the bushing with respect to the liner or sheath or tube.



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***Response to Arguments***

Applicant's arguments submitted under "REMARKS" in the response filed on January 22, 2008 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached on Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
March 27, 2008

/Anu Ramana/  
Primary Examiner, Art Unit 3733

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